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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,962

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Guy Michael Patrick

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,962	<b>Applicant(s)</b> PATRICK ET AL.	
	<b>Examiner</b> MARCELA M. CORDERO GARCIA	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 17-20, 23, 24, 26, 28, 29 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 17-20, 23-24, 26, 28-29, 52-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/15/2010 and 11/15/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is in response to the reply received on 10/27/2010 are pending in the application.

Any rejection from the previous office action, which is not restated here, is withdrawn.

#### ***Election/Restrictions***

2. Applicant's election of Group I, claims 1-20, 23, 24, 26, 28, 29, and 52-54 in the reply filed on February 9, 2010 was previously acknowledged. Applicant's election of the species Cbz-(R)-Phe-(S)-Pro-(R)-Mpg-B(OH)<sub>2</sub> in the reply filed on February 9, 2010 was also previously acknowledged.

#### ***Status of the claims***

3. Claims 1-20, 23-24, 26, 28-31, 34-37, 40, 43-54 were currently pending. Claims 30-31, 34-37, 43-51 were withdrawn as not drawn to the elected group/species. Claims 1-20, 23, 24, 26, 28, 29, and 52-54 were presented for examination on the merits. Upon searching Examiner found other species encompassed by the instant claims which are herein examined for the sake of compact prosecution. As of the response of October 27, 2010, claims 2-9, 11-16, 21-22, 27, 30-51 have been cancelled. Claims 1, 10, 17-18, 20, 26, 28, 52, 54 have been amended. Claims 1, 10, 17-20, 23-24, 26, 28-29, 52-54 are pending and are presented for examination on the merits.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, 10-12, 14-15 were previously rejected under 35 U.S.C. 102(b) as being anticipated by Claeson et al. (US 5,856,306) as evidenced by Elgendy et al. (The Design of Synthetic Inhibitors of Thrombin, 1993).

The rejection is withdrawn in view of Applicant's amendments to the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7, 10-12, 14-15, 20, 23, 26, 28 and 52-54 were previously rejected under 35 U.S.C. 103(a) as being unpatentable Claeson et al. (US 5,856,306) in view of Elgendy et al. (The Design of Synthetic Inhibitors of Thrombin, 1993) and Baschang et al. (US 4,959,394).

The rejection is withdrawn in view of Applicant's amendments to the claims.

8. Claims 8-9, 13, 16-19 and 29 were previously rejected under 35 U.S.C. 103(a) as being unpatentable Claeson et al. (US 5,856,306) in view of Elgendy et al. (The Design of Synthetic Inhibitors of Thrombin, 1993), Baschang et al. (US 4,959,394) and Adams et al. (US 5,780,454).

The rejection is withdrawn in view of Applicant's amendments to the claims.

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 1, 10, 17-20, 23, 24, 26, 28, 29, and 52-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-92 of U.S. Patent No. 7,112,572 in view of Baschang et al. (US 4,959,394).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to an oral dosage form of a compound selected from boronic acids which have a neutral thrombin P1 domain linked to a hydrophobic moiety capable of binding to the thrombin S2 and S3 subsites, and salts thereof, the dosage form comprising a solid phase formulation and include the instantly claimed species (e.g., Cbz-(R)-Phe-(S)-Pro-(R)-Mpg-B(OH)<sub>2</sub>). With regards to the limitation "being adapted for reconstitution of the formulation to form a liquid preparation" the disclosure of US '572 was consulted as a dictionary and it teaches at col.33 that solid dosage forms for oral administration includes powders and granules and may contain a dissolution aid. Further, liquid dosage forms include pharmaceutically acceptable solutions (Col. 34). With regards to the limitation drawn to an effervescent system/tablet in claim 24, it would have been obvious to make effervescent compositions for oral delivery. One of ordinary skill in the art at the time the invention was made would have been motivated to use any kind of oral dosage including effervescent tablets/granules since such kind of delivery was widely known and advantageously applicable to lyophilized drugs as taught, e.g., in Baschang et al. (US 4,959,394). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since Baschang et al. taught that formulations that can be dissolved to form liquid oral forms of administration, such as

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water-soluble powders and effervescent powders, preferably in single dose sachets, effervescent tables or reconstitutable dry syrups, are based on the reaction of a pharmaceutically acceptable organic acid with an alkali metal or alkaline earth metal carbonate compound, in which carbon dioxide is liberated and can be used in the delivery of pharmaceutical compounds which are organic acids (e.g. cols. 5-9) and which are also taught by US '572.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

11. Claims 1, 10, 17-20, 23, 24, 26, 28, 29, and 52-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 7,371,729 (cited in the IDS dated 6/17/2008) in view of Baschang et al. (US 4,959,394). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to an oral dosage form of a compound selected from boronic acids which have a neutral thrombin P1 domain linked to a hydrophobic moiety capable of binding to the thrombin S2 and S3 subsites, and salts thereof, the dosage form comprising a solid phase formulation and include the instantly claimed species (e.g., Cbz-(R)-Phe-(S)-Pro-(R)-Mpg-B(OH)<sub>2</sub>). With regards to the limitation "being adapted for reconstitution of the formulation to form a liquid preparation" column 75 US '729 teaches administering after reconstitution as an aqueous parenteral solution. Although oral administration is not taught by US '729 claims, one of ordinary skill in the art would have been motivated to try other ways of administration such as intranasal and/or oral in order to determine favorable ways of

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administration. With regards to the limitation drawn to an effervescent system/tablet in claim 24, it would have been obvious to make effervescent compositions for oral delivery. One of ordinary skill in the art at the time the invention was made would have been motivated to use any kind of oral dosage including effervescent tablets/granules since such kind of delivery was widely known and advantageously applicable to organic acids as taught, e.g., Baschang et al. (US 4,959,394). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since reasonable expectation of success since Baschang et al. taught that formulations that can be dissolved to form liquid oral forms of administration, such as water-soluble powders and effervescent powders, preferably in single dose sachets, effervescent tables or reconstitutable dry syrups, are based on the reaction of a pharmaceutically acceptable organic acid with an alkali metal or alkaline earth metal carbonate compound, in which carbon dioxide is liberated and can be used in the delivery of pharmaceutical compounds which are organic acids (e.g. cols. 5-9) which are also taught by US '729.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

12. Claims 1, 10, 17-20, 23, 24, 26, 28, 29, and 52-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/592,265 in view of Baschang et al. (US 4,959,394). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications teach compounds such



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as Cbz-(R)-Phe-(S)-Pro-(R)-Mpg-B(OH) and administration to a patient. Although oral administration is not taught by US '265 claims, one of ordinary skill in the art would have been motivated to try other ways of administration such as intranasal and/or oral in order to determine favorable ways of administration. With regards to the limitation drawn to an effervescent system/tablet in claim 24, it would have been obvious to make effervescent compositions for oral delivery. One of ordinary skill in the art at the time the invention was made would have been motivated to use any kind of oral dosage including effervescent tablets/granules since such kind of delivery was widely known and advantageously applicable to organic acids as taught, e.g., Baschang et al. (US 4,959,394). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since Baschang et al. taught that formulations that can be dissolved to form liquid oral forms of administration, such as water-soluble powders and effervescent powders, preferably in single dose sachets, effervescent tables or reconstitutable dry syrups, are based on the reaction of a pharmaceutically acceptable organic acid with an alkali metal or alkaline earth metal carbonate compound, in which carbon dioxide is liberated and can be used in the delivery of pharmaceutical compounds which are organic acids (e.g. cols. 5-9) is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **Applicant's arguments**

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13. With respect to claims 10, 23, 24, 26, 28, 29 and 52-54, Applicants request that this rejection be held in abeyance until otherwise patentable subject matter has been identified in the present application.

### **Response to arguments**

14. The instant ODP rejections have therefore been maintained as set forth above.

### ***Conclusion***

15. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

**16. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

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18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/  
Primary Examiner, Art Unit 1654

MMCG 01/2011